IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, Deceased,	)	
Plaintiff,	)	Civil No. 3:05-0444
	)	Judge Aleta A. Trauger
v.	)	(Dist. Of MA No. 1:05-cv-11515PBS)
PFIZER, INC., *et al.*,	)	
Defendants.	)	

DEFENDANTS' OBJECTIONS TO THE PROPOSED STATEMENT OF PLAINTIFF'S EXPERT CHARLES KING III, PH.D.

Pursuant to the Court's Scheduling Order of April 30, 2010, as amended orally due to flooding in Nashville, Defendants, Pfizer Inc and Warner-Lambert Company LLC (collectively, "Defendants" or "Pfizer") herein submit their objections to the expert witness statement proffered by Plaintiff's expert, Charles King III, Ph.D, who is designated to testify about marketing issues. These objections are in addition to, and without waiving, the objections made by Defendants' motion in limine that was filed and ruled upon by the Court.

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All of fourth ¶ on page 11 – "A study published by Dr. Catherine Fullerton and others . . ."	• Testimony discusses study not disclosed or discussed in Dr. King's expert report or reliance disclosure. (FRCP 26(a)(2)(B).)
First and fifth bulleted ¶¶ on page 2; fourth bulleted ¶ on Slides 1 and 13.	• Dr. King's statements about alleged "suppression" of information on the adverse effects of Neurontin lack foundation, and exceed the scope of Dr. King's expertise as an economist. Dr. King is not qualified to determine the "adverse effects" of Neurontin and is

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	therefore not unqualified to opine whether such adverse effects were "suppressed." (FRE 702/703.)
Slide 3; Second ¶ on page 3 – "This fact was evident to Warner-Lambert. By 1995, Warner-Lambert had analyzed the prospects for Neurontin if marketed only for approved uses and estimated its lifetime future sales would add up to only $500 million. While $500 million seems like a lot of money, it is only a fraction of the total amount of sales actually generated by Neurontin".	• Reference to original estimate for lifetime Neutontin market is irrelevant, misleading and unfairly prejudicial because the referenced estimate is based on epilepsy use only, and Neurontin received FDA approval for PHN, a type of neuropathic pain, after the original estimate. (FRE 402/403)
First ¶ under bulleted list on page 4 – "To settle these criminal charges, Warner-Lambert paid a total of $430 million in criminal fines and reimbursements. Again, $430 million sounds like a lot of money, but it was only a small fraction of the total amount of Neurontin sales that resulted from their illegal off-label marketing activities."	• Dr. King's commentary on penalties paid by Pfizer is irrelevant to any opinion properly stated in Dr. King's statement, and represents legal testimony outside Dr. King's area of expertise. (FRE 402/702)
First two full sentences at top of page 7 – "In the years following Neurontin's initial approval, Warner-Lambert and Pfizer implemented strategies to promote Neurontin for a variety of off-label uses including pain, psychiatric disorders and at doses of more than 1800 mg per day. In each case, off-label Neurontin prescriptions sharply increased after the commencement of off-label marketing campaigns. These strategies included drug company representatives, medical liaisons, and continuing medical education events."	• Discussion of promotion for off-label uses other than the one at issue in this case—neuropathic pain—is irrelevant to any issue related to Mr. Smith's use of Neurontin, or to any alleged duty for Pfizer to test or warn about use of Neurontin in patients with Neuropathic pain. Such testimony is also unfairly prejudicial and likely to confuse the jury concerning the facts at issue in this case. (FRE 402/403)
First 2 ¶s at top of page 8 – " Warner-Lambert sales representatives encouraged doctors to prescribe Neurontin for a variety of off-label uses ***even when there was no evidence to support claims of effectiveness or when studies had shown that the drug was not***	• Statement concerning medical and scientific evidence as to Neurontin's efficacy lies outside Dr. King's expertise as an economist. (FRE 702) • Broad and non-specific statement is

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effective." (emphasis added)	irrelevant and unfairly prejudicial. (FRE 402/403)
Slide 10 and Third ¶ on page 8 – "**[Slide 10]** Company documents show that they targeted psychiatrists, who typically would have no reason to use Neurontin for its approved uses."	• Discussion of promotion to psychiatrists is irrelevant to any issue related to Mr. Smith's use of Neurontin, or to any alleged duty for Pfizer to test or warn about use of Neurontin in patients with Neuropathic pain. Such testimony is also unfairly prejudicial and likely to confuse the jury concerning the facts at issue in this case. (FRE 402/403)
Slide 11	• No objection, but Pfizer requests a limiting instruction that the sponsorship of Continuing Medical Education events by pharmaceutical companies was and is a safe harbor and protected activity under the FDA regulations. They do not constitute promotion and was an acceptable vehicle to disseminate information about the off-label uses of drugs to physicians outside of a "selling" context.
Second ¶ on page 10 – "Pfizer, like Warner-Lambert, had strong economic incentives to continue promoting off-label uses of Neurontin . . . ."	• Commentary on Pfizer's alleged marketing incentives is irrelevant to any qualified opinion being offered. (FRE 402)
First sentence in ¶ 2 on page 13 – "In addition, there is evidence that the suppression of adverse events contributed to increased prescribing of Neurontin."	• Dr. King's statements about alleged "suppression" of information on the adverse effects of Neurontin lack foundation, and exceed the scope of Dr. King's expertise as an economist. Dr. King is not qualified to determine the "adverse events" of Neurontin and is therefore not unqualified to opine whether such adverse effects were "suppressed." (FRE 702/703.)
Portions of ¶ 2, all of ¶ 3 and portion of ¶ 4 on page 13 – "John Marino, Pfizer's Worldwide Team Leader for Neurontin,	• Improper "narrative" testimony absent personal knowledge, which simply recites facts without reference to any

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testified in his deposition before this trial began, that Pfizer has an obligation to share negative results of its exploratory studies with the medical community and that this was the practice at both Warner-Lambert and Pfizer. To suppress or delay a negative study would be misleading and would not present a fair and balanced view, according to Mr. Marino. "The pharmaceutical company's responsibility is to help teach physicians about the risk/benefit profile of appropriate therapies for treatment," including a full explanation of what the risks are, Mr. Marino further testified. Yet Pfizer allegedly took no affirmative action to disclose what it knew about problems with Neurontin. John Marino admitted that, as far as he was aware of, Pfizer has never sent out a "Dear Doctor" letter to physicians about Neurontin for the treatment of bipolar disorder or any other use. Having spent considerable time and money communicating positive messages about Neurontin to doctors, Pfizer devoted fewer resources to re-educating doctors when the news about Neurontin was negative."	proper expert opinion or analysis, and is not reasonably tailored to explain the basis for any qualified opinion being offered. (FRE 602, 703.) • Testimony concerning allegations about efficacy in relation to bipolar disorder or use by psychiatrists are irrelevant to the prescription and use by Mr. Smith and unfairly prejudicial. (FRE 402/403)
First sentence in second full ¶ on page 14 – "Doctors would consider this information material to their decisions to prescribe Neurontin and it would have affected their behavior."	• This statement is vague and ambiguous as to whether the referenced "doctors" are the particular physicians who prescribed Neurontin for Mr. Smith. To the extent it refers to doctors other than Dr. Mackey, the prescribing doctor in this case, the statement is irrelevant. To the extent it refers to Dr. Mackey, the statement is speculative, and is not the proper subject of expert testimony, particularly given that Dr. Mackey has provided deposition testimony, and may appear at trial. As stated, the sentence if likely to confuse and mislead the jury as to the proper questions at issue relating to Plaintiff's

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	inadequate warning claim; *i.e.*, whether ***Dr. Mackey***, rather than some other, unidentified physician, would find information material to his decision to prescribe Neurontin for Mr. Smith. Finally, Dr. King is not qualified, as an economist, to determine who particular risk information would affect any doctor's behavior. (FRE 402/403/702.)
Second sentence in second full ¶ on page 14 – "I understand that although the mode of action of Neurontin was unknown when the drug was originally approved, it is now known that Neurontin depletes serotonin and neuropinephrine and that low levels of these neurotransmitters are an established risk factor for depression and suicide."	• Dr. King's comments on the neurochemical properties of Neurontin represent unqualified opinions about the safety and efficacy of Neurontin, the meaning or significance of particular research findings or studies about Neurontin, or the propriety of medical research or publication practices. (FRE 702.)
Slide 13 and First sentence in first full ¶ on page 15 – "Thus suppression of adverse information about Neurontin further enabled Neurontin off-label sales. **[Slide 13]"**	• Dr. King's statements about alleged "suppression" of information on the adverse effects of Neurontin lack foundation, and exceed the scope of Dr. King's expertise as an economist. Dr. King is not qualified to determine the "adverse effects" of Neurontin and is therefore not unqualified to opine whether such adverse effects were "suppressed." (FRE 702/703.)
Page 1, Third bullet; Page 2, fourth bullet, Slide 1, third bullet, and similar testimony about the "effects" of off-label promotion on "all or substantially all" physicians.	• Improper expert opinion that is unsupported by any foundation or quantitative analysis and invites jury speculation on the cause of Mr. Smith's physician to prescribe Neurontin to Mr. Smith. (FRE 702/402/403)

Dated: May 12, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 12th day of May 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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